

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-478 / S -007

CHEMISTRY REVIEW(S)

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| CHEMIST'S REVIEW | | 1. ORGANIZATION DACCADP, HFD-170 | 2. NDA Number(s) 20-478 |
| 3. Name and Address of Applicant (City & State): Abbott Laboratories D-389, Bldg. AP30 200 Abbott Park Road Abbott park, Illinois 60064-6157 | | 4. AF No. | 5. Supplement(s) Number(s) Date(s) SLR-007 08/21/00 |
| 6. Drug Name: Ultane® | 7. Nonproprietary Name: Sevoflurane | 8. Amendments & Other (reports, etc) - Dates | |
| 9. Supplement Provides For: A revised package insert and carton label for Ultane® that includes besides other minor changes, a statement that at least _____ | | | |
| 10. Pharmacological Category: Anesthetic | 11. How Dispensed: <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC | 12. Related IND(s)/ NDA(s)/DMF(s) | |
| 13. Dosage Form(s): Volatile Liquid | 14. Potency(ies): 250 ml bottle | | |
| 15. Chemical Name and Structure: 1,1,1,3,3,3-Hexafluoro-2- (fluoromethoxy) propane; Fluoromethyl 2,2,2-trifluoro-1-(trifluoromethyl) ethyl ether. C ₄ H ₃ F ₇ O | | 16. Records/Reports Current: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| 18. Conclusions and Recommendations: The supplement is approvable pending the deletion of _____ atement from the labeling. Comment listed at the end should be included in the AE letter. CC: Original NDA# 20-478 HFD-170/Division File HFD-170/Chemist/Harapanhalli HFD-170/CSO/Basham R/D initialed by : DKoble | | | |
| 19. REVIEWER | | | |
| Name Ravi S. Harapanhalli, Ph.D. | Signature | Date Completed May 23, 2002 Revised 08/01/02 | |

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/s/

Ravi Harapanhalli
8/1/02 03:12:18 PM
CHEMIST

Please sign off

Dale Koble
8/1/02 03:54:36 PM
CHEMIST